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Environmental Technology Verification Program

Advanced Monitoring Systems Center

Quality Management Plan (QMP) for the ETV Advanced Monitoring Systems Center Version 4.0

QUALITY MANAGEMENT PLAN (QMP)

for the

ETV ADVANCED MONITORING SYSTEMS CENTER
Version 4.0

(SIGNATURE ON FILE)

Robert Fuerst	12/17/02
EPA CENTER MANAGER	Date
Elizabeth Betz	12/17/02
EPA CENTER QUALITY MANAGER	Date
Karen Riggs	12/9/02
BATTELLE CENTER MANAGER	Date
Zachary Willenberg	12/9/02
BATTELLE QUALITY MANAGER	Date

BATTELLE
505 King Avenue
Columbus, OH 43201

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1.0 GENERAL PROVISIONS

1.1 INTRODUCTION

1.1.1 This document, the Quality Management Plan (QMP) for the Advanced Monitoring Systems (AMS) Center describes the quality systems that will be employed by Battelle in conducting the AMS Center. These systems are designed to be consistent with ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs", and the U. S. Environmental Protection Agency (EPA) document "Environmental Technology Verification Program *Quality and Management Plan for the Pilot Period (1995-2000)*", Version 1.0, dated May 1998.

1.2 PURPOSE

1.2.1 The purpose of the AMS Center is to verify commercially-available systems for monitoring natural species and contaminants in air, water, and soil. The AMS Center encompasses the full range of environmental monitoring technologies and as part of the larger Environmental Technology Verification (ETV) program, is designed to provide technology users with objective, high quality performance data for air, water, and soil monitoring systems that will support technology selection decisions.

1.3 SCOPE AND FIELD OF APPLICATION

1.3.1 This document encompasses activities that Battelle as an EPA verification partner (VP), shall utilize to assure the quality of products and services provided for the AMS Center. The AMS Center is one of 6 centers operating under the ETV program.

1.3.2 This QMP applies to personnel and activities conducted for the ETV AMS Center and contains the minimum specifications and guidelines that are applicable to ETV AMS Center quality management functions and activities based upon ANSI/ASQC E4-1994. This includes, but is not limited to, personnel qualification and training, procurement of items and services, documents and records, computer hardware and software, planning, implementation for work processes, assessment and response, and quality improvement provisions.

1.4 BACKGROUND

1.4.1 Battelle (Memorial Institute) was established in 1929 by Gordon Battelle and serves as a memorial to his family. Governed by a self-perpetuating Board of Trustees, Battelle is a nonprofit Ohio corporation. Battelle has a worldwide staff of 8,000 scientists, engineers, and supporting specialists. Each year, thousands of studies are in progress at Battelle's various business operations. These programs are performed for some 2,000 companies and government agencies. Battelle's business volume is nearly $1 billion a year.

Battelle's headquarters are in Columbus, Ohio. Major technology centers are located in Columbus; Richland, Washington; Amarillo, Texas; and Geneva, Switzerland. Battelle manages the Pacific Northwest National Laboratory in Richland, Washington and co-manages

Brookhaven National Laboratory in Long Island, New York and Oak Ridge National Laboratory for the U.S. Department of Energy. Specialized facilities, regional centers, and offices are located in more than 40 other cities in the United States and Europe.

Battelle's organization includes 16 business sectors. The AMS Center is managed within Battelle's Environmental Business sector. The Environmental Business sector includes approximately 500 chemists, engineers, statisticians, and support personnel. Staff and facilities will be drawn from the Environmental Business and other Battelle sectors to support the AMS Center. Staff involved in the AMS Center include those with expertise in environmental monitoring, stakeholder involvement and project promotion and communication. Key Battelle facilities that are available for use on the AMS Center include comprehensive laboratory analysis equipment; field sampling and analysis equipment; source simulators such as pilot plants; environmental chambers; and real-world test sites.

The organization chart for the AMS Center is provided in Figure 1.0 and shows key AMS Center staff and their reporting lines. The key AMS Center staff are:

Battelle Center Manager: Ms. Karen Riggs is Battelle's AMS Center manager with responsibility for meeting all technical, budget, and schedule goals for the Center. Ms. Riggs reports directly to Dr. Gregory Mack, a Vice President in the Environmental Business Sector. Dr. Mack will provide Ms. Riggs and the other key AMS Center staff with direct support in securing and deploying Battelle resources for the AMS Center. Mr. Kovacs, manager of Battelle's Environmental Business sector, has ultimate responsibility for ensuring that necessary Battelle facility and staff resources are available to support the AMS Center. Ms. Riggs serves as the primary point of contact for EPA's Center Manager, Mr. Robert Fuerst. She also directs the activities of the four technical leaders assigned to major tasks on the Center.

Battelle Quality Manager: Mr. Zachary Willenberg is the Battelle Quality Manager for the AMS Center. He is the Quality Assurance Auditor for Battelle's Atmospheric Science and Applied Technology department and reports directly to Battelle Vice President Dr. Mack, and for the AMS Center, to Ms. Riggs. These relationships are illustrated in Figure 1.0.

Verification Testing Leader: Dr. Thomas J. Kelly and Ms. Amy Dindal are the AMS Center Verification Testing Leaders and have responsibility for developing verification protocols and test/QA plans and planning and leading verification tests. Dr. Kelly is a Senior Research Scientist and Ms. Dindal is a Research Scientist in Battelle's Environmental Business sector. They report directly to Ms. Riggs on their AMS Center activities.

Stakeholder Involvement Leader: Ms. Gretchen Hund is the AMS Center Stakeholder Involvement Leader with primary responsibility for stakeholder recruitment, communications, and meetings. Ms. Hund is a Research Leader at Battelle and reports directly to Ms. Riggs on the AMS Center.

Promotion and Communications Leader: Ms. Helen Latham leads promotion and communications activities on the AMS Center. Ms. Latham is a Communications and Outreach Specialist at Battelle and reports directly to Ms. Riggs on her AMS Center activities.

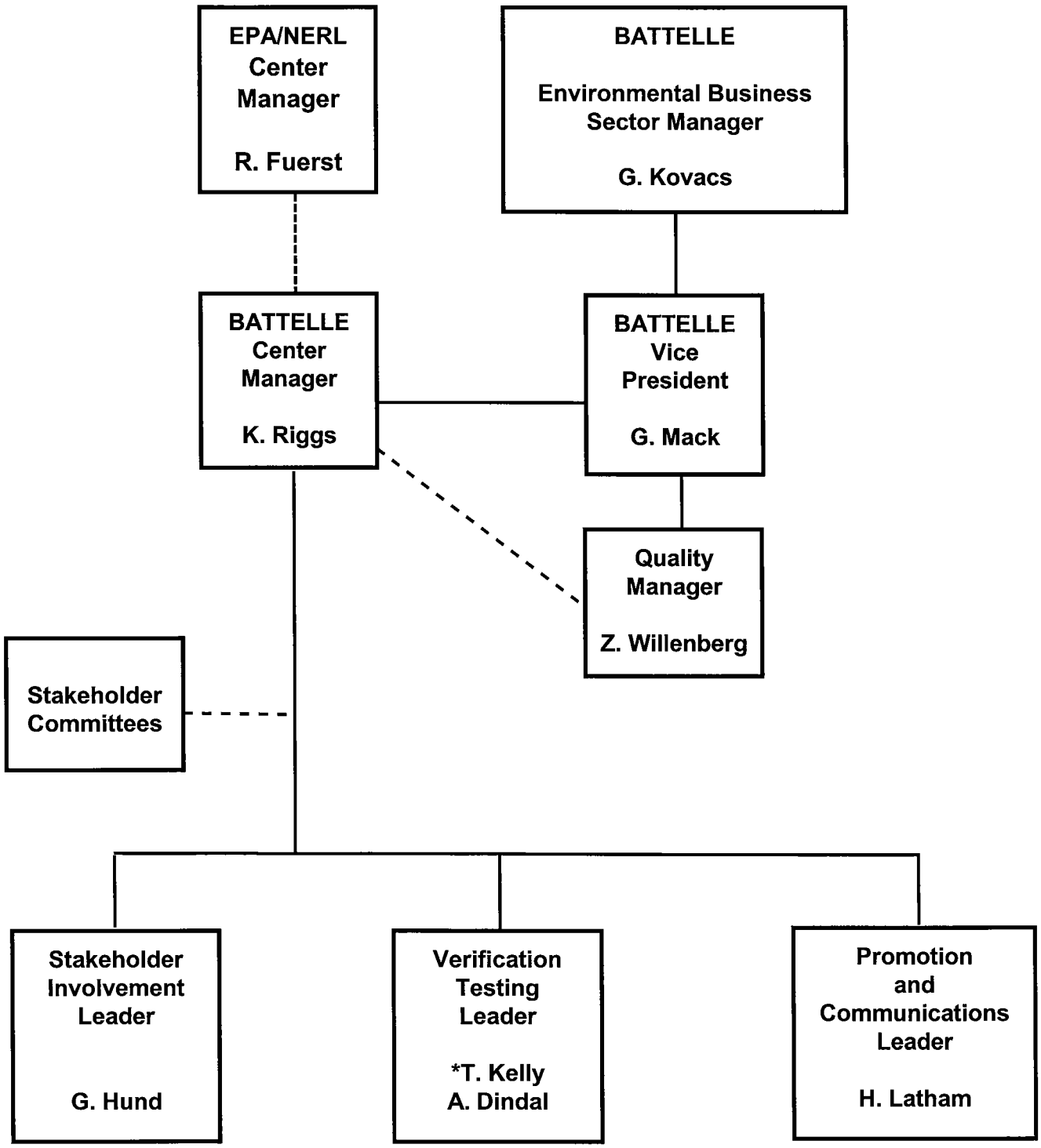

Figure 1.0 AMS Center Organization
(dotted lines indicate indirect reports)
*denotes lead

Names, mailing/email addresses, and phone/facsimile numbers of these Battelle AMS Center key staff are included in Appendix I.

1.5 DEFINITIONS

1.5.1 Verbs for clarity:

Shall, must: when the element is required and deviation from the specification will constitute nonconformance with this QMP

Should, will: when the element is recommended

May: when the element is optional.

1.5.2 **Center quality management plan (QMP)** - Procedures for quality-related activities developed and implemented by Battelle to assure quality in the work processes and services developed for the AMS Center.

Generic verification protocol - the protocol developed to define the verification process for the AMS Center.

Stakeholders - Representatives of verification customer groups including buyers and users of technology, consulting engineers, finance and export communities, and government permitters and regulators. Stakeholders are selected based upon their expertise and interest in environmental monitoring and their availability and willingness to participate in the AMS Center. A list of AMS Center Air and Water Stakeholder Committee members, addresses, and phone numbers are available upon request.

Test/quality assurance (QA) plan - the plan developed by Battelle, with appropriate input for each individual test of a technology or technology class; this plan may include more than one technology. The test/QA plan provides the experimental approach with clearly stated test objectives and associated quality objectives for the related measurements and may incorporate or reference the AMS Center generic verification protocol and/or standard operating procedures (SOPs).

Vendor - An individual, company, or organization which has the authority to submit an environmental monitoring technology for verification testing.

Verification partner - a public or private sector organization selected by EPA to cooperate with the implementation of the ETV program by conducting verification testing and to provide unbiased and objective test performance data on environmental technologies.

Verification partner Center manager - the person designated by the verification partner with the responsibility to manage the Center and serve as the chief point of contact with the EPA.

Verification partner quality manager - the person designated by the verification partner with the responsibility to manage quality assurance for the AMS Center on behalf of the verification partner Center manager.

Verification report - a complete detailed summary of procedures and results for a single verification test on a single technology.

Verification statement - a summary statement developed by Battelle and approved by EPA, which reports quantitatively but without endorsement, the performance of a tested technology in a verification test. An example of an ETV verification statement is included in Appendix II.

2.0 MANAGEMENT SYSTEMS

Battelle's quality policy is to provide services, products, and data of the highest quality that meets or exceeds our client's requirements and expectations. To this end, quality programs such as this AMS Center QMP, and quality achievement, shall be fully supported by Battelle management and staff.

2.1 MANAGEMENT AND ORGANIZATION

2.1.1 Battelle management is responsible for committing to a quality policy and for creating work environments in which all personnel strive for the highest quality of services and products. Management shall also provide the Battelle Center Manager the authority to ensure the following:

- that all applicable elements of the quality system as described in this QMP are understood and are implemented in the AMS Center.
- that adequate personnel and resources are available to plan, implement, assess, and improve services and products relevant to the AMS Center.
- that staff is (are) clearly designated to stop unsafe work and work of inadequate quality as affects the AMS Center.

2.2 QUALITY SYSTEM AND DESCRIPTION

2.2.1 The Battelle quality system to be implemented for the AMS Center according to this QMP (and, historically, previous versions of this QMP) is intended to conform with the specifications listed in:

- ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality and Management Plan for the Pilot Period (1995-2000)*", Version 1.0, May 1998.

2.2.2 The principal quality system document governing general and specific responsibilities for AMS Center management and staff, responsibility and authority for all technical activities, and reporting lines is this document, the "Quality Management Plan for the ETV Advanced Monitoring Systems Center".

Individual verification tests will conform both to this QMP and the applicable test/QA plan document(s) and applicable Standard Operating Procedures (SOPs).

The AMS Center QMP and any revisions will be controlled documents identified by a unique Battelle document number (QMP Section 2.5.1) and will be distributed according to a published list maintained by the Battelle Quality Manager.

The QMP review will be documented by the Battelle Quality Manager and Battelle Center Manager by signing and dating the copy of the QMP routed for review. Any revisions to the QMP will be compiled by the Battelle Quality Manager for review, approval, and distribution. The approved QMP has a scheduled review interval of one (1) year.

The initial approved QMP will serve as Version 1.0, which will be designated, with its effective date, in the upper right corner of each document page. Revisions will be so designated beginning with '2.0' and will subsequently be numbered and dated as applicable. Battelle staff to whom controlled copies are issued will be responsible for disposal of outdated QMP versions.

2.2.3 The scope of the AMS quality system applies to all Battelle personnel providing products and services for the AMS Center. All AMS Center key staff shall be knowledgeable regarding the QMP requirements.

2.2.4 Quality procedures documentation includes maintenance of all inspection and review/assessment records, listing of all controlled documents (QMP Section 2.5.1), and retention of records pertaining to personnel training and qualification, instrument maintenance and calibration, and test methods/operating procedures.

2.2.5 Center-specific quality controls are initiated upon approval of Battelle's QMP prior to implementing any verification testing activities. Planning actions documented through approved test/QA plans shall also serve as quality control mechanisms for verification testing.

In-process quality controls, through conduct of inspections followed by assessment reports and verification of corrective actions when required, shall also be performed and recorded.

Implementation of a complete and consistent assessment of technical operations provides overall control of Center activities. This will be accomplished by the Battelle Quality Manager according to Section 3.0 in this QMP.

2.2.6 An external management system review (MSR) of the Battelle quality system will be performed at least once by the EPA Quality Manager. In addition, an independent technical systems audit will be performed by the EPA ETV Quality Manager or designee, at least two times for the AMS Center.

2.3 PERSONNEL RESPONSIBILITIES, QUALIFICATIONS, AND TRAINING

2.3.1 Responsibilities

2.3.1.1 Verification Partner Responsibilities. In accordance with EPA's ETV QMP dated May 1998, Battelle's Verification Partner responsibilities for the AMS Center include the following:

- establish, attend, and/or conduct meetings of stakeholder committees with representation from major customer groups

- maintain communication with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures
- manage the oversight and conduct of verification activities
- assure that quality procedures are incorporated into all aspects of the AMS Center
- develop, conduct, and/or oversee test/QA plans in cooperation with technology vendors
- solicit technology vendor proposals or vendor products
- operate ETV activities within the documented quality system
- prepare ETV verification reports and statements at the completion of each technology verification
- appoint a quality manager, responsible for ensuring that the ETV AMS Center quality systems are in compliance with E-4, and that ETV AMS Center complies with this QMP.

2.3.1.2 Key Staff Responsibilities. Battelle is committed to operate an effective quality system that ensures compliance with all program requirements. The responsibilities of Battelle key staff who will be performing verification testing activities addressed by this AMS Center QMP are listed in Table 1.0.

2.3.1.3 Stakeholder Responsibilities. Their responsibilities for the AMS Center include the following:

- Assist in development of the generic verification protocol
- Assist in prioritizing the types of technologies to be verified
- Review Center-specific procedures and AMS Center documents including test/QA plans, verification reports, and verification statements
- Assist in the definition and conduct of outreach activities appropriate to the technology area and customer groups
- Serve as information conduits to the particular constituencies that each member represents.

Table 1.0. Personnel Responsibilities for the AMS Center for Verification Testing Activities

AMS Center Team Member	Responsibilities
Battelle Center Manager Karen B. Riggs	• Ultimate responsibility for all aspects of the AMS Center
	• Conduct and oversee activities to establish and maintain an active stakeholders committee
	• Maintain adequate communication with EPA
	• Manage oversight and conduct of verification activities
	• Assure that quality procedures are incorporated and implemented
	• Review/approve test/QA plans
	• Solicit technology vendors
	• Operate ETV activities within the documented quality system
	• Review, and approve verification reports
	• Review, and approve verification statements
Battelle Verification Testing Leaders Thomas J. Kelly and Amy Dindal	• Coordinate planning, performance, and data reviews of technology verification testing consistent with the AMS QMP requirements
	• Coordinate review of applications from technology vendors wanting to have their technology verified
	• Work with stakeholders and EPA to identify and prioritize technologies for verification
	• Schedule verification tests
	• Select/assembly Verification Team to perform specific technology verification test/data reviews
	• Develop and implement test/QA plans
	• Prepare, review, and/or approve verification reports

Table 1.0. (Continued)

AMS Center Team Member	Responsibilities
	• Prepare, review, and/or approve verification statements
	• Oversee/assist in problem resolution involving verification tests
	• Review/approve results from verification testing or vendor-supplied data review
Battelle Quality Manager Zachary J. Willenberg	• Ensure that the quality system is compliant with EPA-specified standards
	• Advise the Battelle Center Manager of any QA/QC problems and oversee corrective actions
	• Ensure that the QMP includes sufficient and appropriate specifications for QA/QC as required for the AMS Center
	• Interact with AMS Center management and technical personnel to ensure that QA/QC procedures are understood
	• Ensure that Battelle QMP, the EPA/ETV QMP, and the ANSI/ASQC E4 document are followed for performing system inspections and audits
	• Ensure that inspection reports are prepared and distributed that detail appropriate corrective action and that implementation will be responded to by personnel and returned to the Battelle Quality Manager. Problems that are not addressed will be brought to the attention of management
	• Review test/QA plans and SOPs
	• Review all quality system documentation, including this document, at intervals necessary to ensure their integrity. Such reviews will be recorded and documents will be revised if necessary. All previous original (i.e., signed) revisions will be retired and archived.
	• Act as a QA resource to respond to quality needs and problems. Answer questions and train laboratory staff in QA/QC requirements and procedures.

Table 1.0. (Continued)

AMS Center Team Member	Responsibilities
Battelle Technical Staff	• Provide technical support to verification testing as needed, and interact with the Battelle Quality Manager during inspections and implementation of corrective actions when needed
	• Perform QA/QC activities specified in this document, applicable test/QA plans, and in pertinent SOPs
	• Conduct quality control measures and activities required for sample analyses
	• Evaluate results of quality control analyses to determine if quality goals and objectives have been met
	• Inform the Verification Testing Leader of potential quality control problems
	• Perform corrective action at the direction of Center management and Battelle Quality Manager
	• Document results of quality control analyses and include them with sample results and historical data files
	• Maintain instrumentation in accordance with the QMP, test/QA plan, SOPs, and the manufacturer's instructions

2.3.2 Qualification and Training

Battelle personnel qualification and training shall target technical work performed directly in support of verification testing activities. These qualifications and training may include:

- Formal education in physical sciences (i.e., chemistry, physics, engineering)
- Experience in sampling and analysis of air, water, and soil
- Training on standard analytical instrumentation such as gas chromatographs, mass spectrometers, Fourier transform infrared spectrometers, etc.
- Experience in designing experiments to verify monitoring technologies
- Experience with unique monitoring techniques such as immunoassay, fiber optics, etc.

Battelle personnel working on the AMS Center shall have, at a minimum, documentation, maintained by Battelle permanently, for each of the following:

- Education history which can include formal qualification or certification relevant to technical, quality assurance, or management disciplines.
- Work experience as academic or on-the-job performance in technical and/or management areas.
- Experience in the application of quality assurance/quality control requirements in technical performance or data verification.

2.3.2.1 Formal qualifications and certifications in the form of actual or verified-copy documentation for specific disciplines shall be maintained in the staff member's qualification/training file.

2.3.2.2 Technical management and training received in-house or offsite shall be recorded and forms, memos, or certificates retained. Performance on either task, project, or program assignments is to be considered as part of training.

2.3.2.3 Retraining needs based on job requirements shall be determined by the staff member and respective management. To maintain staff proficiency, opportunities provided by Battelle or other sources shall be made available, preferably on an annual basis.

2.3.2.4 Personnel job proficiency based on witnessed performance on-the-job by a qualified trainer/staff member designee shall be documented. Specific method requirements for instrument inspection, performance, and maintenance are objective measures that could be considered. Specific performance based on national certification requirements can be recorded with certificates or other documentation. Basic areas of proficiency for verification testing may include, at a minimum:

- sample management practices, such as chain of custody records
- sample handling and storage and use of standards and reagents
- instrument inspection, use, and maintenance
- data acquisition, analysis, and verification.

2.3.2.5 Training resources should be offered on-site by Battelle for facility requirements, such as general computer software use (E-mail, spreadsheets) or project management. Off-site training, project/program meetings, and technical society membership should be available for specific disciplines contributing to the staff member's overall job proficiency.

2.3.2.6 Participants working on behalf of Battelle in support of the AMS Center and/or individual test operations are expected to provide the Verification Testing Leader, or designee, with:

- educational background and/or degree(s) relevant to technical areas represented in the AMS Center
- work experience related to the technology category undergoing verification.

2.4 PROCUREMENT AND ACCEPTANCE OF ITEMS AND SERVICES

2.4.1 Policy

Procurement technical and quality requirements are generally based upon value (cost, durability, maintainability), performance (specification compliance, operating conditions, calibration capacity), delivery (timeliness, ease of ordering), customer support (responsiveness, technical ability); and completeness and coherence of instructions (clarity, accuracy).

2.4.2 Procurement

Technical and quality requirements for items and services procured for a specific verification test shall be included in the test/QA plan. These requirements will typically be specified under materials and/or measurement system equipment. The request for items or services will initiate from the Verification Testing Leader or technical staff with approval for purchase from the Battelle Center Manager or designee.

2.4.3 Acceptance

2.4.3.1 Testing equipment procured for activities affecting quality shall be calibrated to ensure accuracy with required specifications listed in the test/QA plan. Any discrepancies shall result in the return of the item to the supplier. Verification, storage, and maintenance records will be included in individual verification test records.

2.4.3.2 Testing materials procured for activities affecting quality (e.g. reference standards or gases) shall be accompanied with a Certificate of Analysis (COA). The COA will be examined to ensure that the listed specifications are within the required limits. The COA will be retained and included in the verification test records.

2.5 DOCUMENTS AND RECORDS

2.5.1 Controlled Documents

Document control is the system which ensures that only the latest revision of the defined documents are used by Battelle staff participating in the ETV AMS Center. The system includes retention of the document with original signed page(s) in limited access storage area, a unique numbering system for all documents (typically identified by revision number and/or date), and a distribution list for each document. Such documents are defined as "controlled documents" and can be revised only by the personnel listed within each document or this QMP. The following is a list of the controlled documents within the ETV AMS Center:

- Quality Management Plan for the ETV Advanced Monitoring Systems Center
- Standard Operating Procedures
- Test/QA plans
- Generic Verification Protocol for the AMS Center.

Controlled document identification will consist of a number, date, and version, if applicable, assigned to the document by the Battelle Quality Manager or designee. A current Master List of Controlled Documents and Distribution shall be maintained by the Battelle Quality Manager.

As a controlled document, approved copies of the QMP will be maintained and issued to AMS Center staff by the Battelle Quality Manager or designee.

Obsolete or superseded documents shall be removed from operations when new documents are provided. Notification will accompany new document versions that the previous version is to be removed from use and destroyed. Staff members are responsible for destroying outdated versions of documents assigned to their person. The Battelle Quality Manager is authorized to remove outdated documents observed during inspections and reviews. All controlled documents, including historical revisions, will be retained at least seven years after final payment of the cooperative agreement, with the exception of the Standard Operating Procedures which will be permanently archived.

2.5.2 Study Records

2.5.2.1 Active Study Records. All study records shall carry minimum identification pertaining to title, responsible person or author, and date. All manual entries shall be entered using ink and no changes to entries, manual or electronic, shall obscure the original record during the correction process, and shall be initialed and dated by the individual recording the entry. A short explanation will be added to non-obvious corrections.

2.5.2.2 Storage of Study Records. Verification test records specific to the AMS Center shall be retained for at least seven years after final payment of the cooperative agreement. All AMS Center records needed to both reconstruct test activities and verify that reported data were collected in a quality manner reconciled to this QMP and AMS Center requirements will be maintained in an appropriate area of limited access until

either transferred to EPA ORD Records Management or properly destroyed with EPA permission. The Battelle Quality Manager will retain, as permanent record, documentation of the transfer or destruction of Battelle's AMS Center records.

2.5.3 ETV Program Records

The following program records will be retained, as per ETV directives, for at least seven years after final payment of the cooperative agreement.

- Minutes of stakeholder meetings
- Cooperative agreement records
- Verification reports
- Verification Statements
- Battelle quality assessment reports.

2.5.4 Record Preparation, Review, Approval, and Distribution

Responsibilities for these activities are summarized in Table 2.0 and are detailed below.

2.5.4.1 Preparation. Individual case requirements and this QMP shall guide document and record content and/or format. For the AMS Center, guidance for content and/or format are derived by EPA/ETV directive and the following documents:

- EPA document "Environmental Technology Verification Program *Quality and Management Plan for the Pilot Period (1995-2000)*", May 1998, or most current version.

- ETV Program Web Page (specific content and format for verification statements).

- ANSI/ASQC E4-1994. *Specfications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.*

- EPA QA/R-5. *EPA Requirements for Quality Assurance Project Plans.*

2.5.4.2 Review/Approval. Record review/approval shall be performed by qualified technical and/or management personnel as deemed appropriate. The individual reviewer shall have access to all needed references.

All prepared documents in QMP Sections 2.5.1 through 2.5.3 shall require at least one review by a Battelle staff member prior to external distribution by Battelle. Document and record reviews are performed at the request of the Battelle Center Manager, Quality Manager, Verification Testing Leader, or other staff personnel.

Table 2.0 Records Management Responsibilities for the AMS Center

Record Type	Preparation/Updating	Review	Approval	Finals Distributed to:
ETV Verification Strategy	N/A	Battelle Center Manager	N/A	N/A
ETV Quality and Management Plan	N/A	Battelle Center Manager	N/A	N/A
COAG/IAG Records	Battelle Center Manager	N/A	N/A	N/A
AMS Center Quality Management Plan	Battelle Quality Manager	EPA Quality Manager	EPA Center Manager EPA Quality Manager Battelle Center Manager Battelle Quality Manager	Testing Staff ETV Webmaster EPA Quality Manager EPA Center Manager
Minutes of Stakeholder Meetings	Battelle	EPA Center Manager Stakeholders	N/A	Stakeholders ETV Webmaster EPA Center Manager
Generic Verification Process Protocol	Battelle	EPA Quality Manager Stakeholders	EPA Center Manager	ETV Webmaster (draft and final versions) EPA Center Manager
Test/QA Plan (including SOPs)	Battelle	Battelle Quality Manager EPA Quality Manager EPA Center Manager Assigned Stakeholders	Vendors EPA Center Manager	Testing Staff Vendors EPA Center Manager EPA Quality Manager
Generic Test/QA Protocol	Battelle	N/A	EPA Center Manager	ETV Webmaster EPA Center Manager
Raw data	Battelle	N/A	N/A	EPA can request copies
ETV Verification Report	Battelle	EPA Quality Manager Vendor	EPA Center Manager	ETV Program Director EPA Center Manager Vendors
ETV Verification Statement	Battelle	EPA Center Manager EPA Quality Manager Vendor ETV Program Director	EPA Laboratory Director	ETV Webmaster EPA Center Manager Vendors
Annual ETV Progress Report	N/A	Battelle Center Manager	N/A	N/A
EPA Reviews/Audit Reports	N/A	N/A	N/A	Battelle Center Manager Battelle Quality Manager
Battelle Reviews/Audit Reports	Battelle Quality Manager	Battelle Center Manager Battelle Verification Testing Leader	N/A	EPA Center Manager EPA Quality Manager

NA = Indicates Battelle does not have responsibility for preparing/updating record; conducting or obtaining review; providing or obtaining approval; or distributing and/or receiving final record.

In addition, ETV record review assigned to Battelle extends to the following documents, at a minimum, according to the ETV QMP of May 1998:

- EPA/ETV strategy
- EPA/ETV QMP
- Annual Center progress reports.

2.5.4.3 Distribution. Once records have been reviewed and approved as required, distribution will be made as listed in Table 2.0 which is based upon the ETV QMP of May 1998. AMS Center documents specifically requiring EPA approval before release include:

- AMS Center QMP
- Generic verification protocol
- Test/QA plan
- ETV verification report
- ETV verification statement.

2.6 COMPUTER HARDWARE AND SOFTWARE

This QMP requires that Battelle staff understand the necessity for all computer hardware and software specifications. Staff shall attempt to utilize computer hardware and software within the acceptance criteria specified, and assures that hardware and software are installed, maintained, and used according to specifications. Any time a change in hardware components or configuration or a software modification is needed, retesting and recalibration must be performed and documentation included with facility records.

2.6.1 Hardware

All computer hardware at Battelle contains Intel based Pentium processing running a Microsoft operating system. Each personal computer (PC) primarily consists of a standard complement of Microsoft software (e.g. Word, Excel, Access, PowerPoint, and Outlook) with capabilities of running other commercial software (e.g. WordPerfect, Quattro, Lotus, SAS,) and delivery of data in any standard format.

Computer hardware is upgraded to improve performance and provide complete compatibility with current standards. The decision to upgrade computer hardware is made when a project that requires specific computer capabilities is received. Next, an assessment of impact is completed. This assessment includes a review of current computer programs and the impact or upgrading hardware on data accessibility.

2.6.2 Software

Specific software required for a verification test will be identified in the test/QA plan. Most software used at Battelle is acquired commercially, loaded, and tested as specified by the publisher. Independently-developed software is not used within the ETV AMS Center, only commercial products are used. Software used for data management activities may include

Microsoft Excel or Access. Standard word processing software (e.g. WordPerfect, Word) is used to create reports.

2.6.3 Validation Policy

Since all hardware and software used on the ETV AMS Center is commercially available, and wide public use and continued market viability is considered proof of software dependability, validation is not considered necessary. However, verification of data analysis techniques within each program (e.g. the use of formulas and macros) is required. For each defined spreadsheet a performance test document will be prepared which will contain the following:

- An overview of the application. The overview will describe what the application is required to do and specify the methods used to meet the predetermined requirements.
- References to the productivity software used (e.g., Excel 97, SAS for Windows V6.12, etc), and the operating system (e.g., Windows 95, Windows NT, etc.).
- A description of important equations used to derive data.
- A description of what test(s) were conducted to confirm the accuracy of the application.

2.7 PLANNING

This QMP addresses the purpose and scope of systematic, timely, and effective planning necessary to assure services and products of the highest quality.

2.7.1 Stakeholder committee(s) containing representatives of appropriate technology interest groups shall be jointly established by the EPA Center Manager and Battelle. Individual stakeholders shall be selected for these committee(s) based on their expertise and interest in environmental monitoring and their availability and willingness to participate.

A joint meeting of the EPA Center Manager, Battelle, and stakeholder committees will be held at least once annually, with minutes of this meeting recorded, reviewed, and circulated to the stakeholders, the ETV Center Manager, and the ETV Webmaster.

The planned quality-related purposes of this meeting are to:

- Identify, revise, and/or clarify the technical and quality goals of the work to be accomplished
- Consider any cost and schedule constraints within which test activities are required to be performed
- Determine testing priorities and evaluate customer satisfaction
- Review verification plans.

2.7.2 Systematic Planning of Verification Tests

An overall view of the EPA ETV verification process is shown in Figure 2.0. Battelle, in cooperation with the EPA Center Manager, begins a systematic process to plan the individual verification tests. Systematic planning may be accomplished through any demonstrated technique such as the data quality objectives process (EPA QA/G-4 Guidance for the Data Quality Objectives Process). The planners perform the following actions:

- refine the scope of respective technology areas
- determine interest in verification from the vendors of commercial-ready technologies within the defined scope of these areas
- convene stakeholder committees containing representatives of verification customer groups which advise during the planning process
- mediate and facilitate the selection of prioritized technologies
- prepare test/QA plan(s) which are developed to promote uniform testing for a given type of technology
- coordinate the review and revision of the test/QA plan(s) (see the review and approval scheme in Table 2.0) keeping in mind both the customers and EPA's objective for verification as defined in the ETV Strategy
- solicit vendor agreements to participate in verification of their products based on the test/QA plan
- prepare final test/QA plans after testing a given type of technology which includes revisions based on actual test experience.

Systematic planning process-control documents for the AMS Center include:

- The ETV Program Policy Compendium
- The ETV Program QMP
- This QMP which defines the operational quality system necessary to provide acceptable products and services.
- Written quality procedures specific to the technology and verification test including test/QA plans and Standard Operating Procedures.
- Outputs from stakeholder committee meetings in the form of reviewed and distributed minutes.
- Monthly internal cost reports

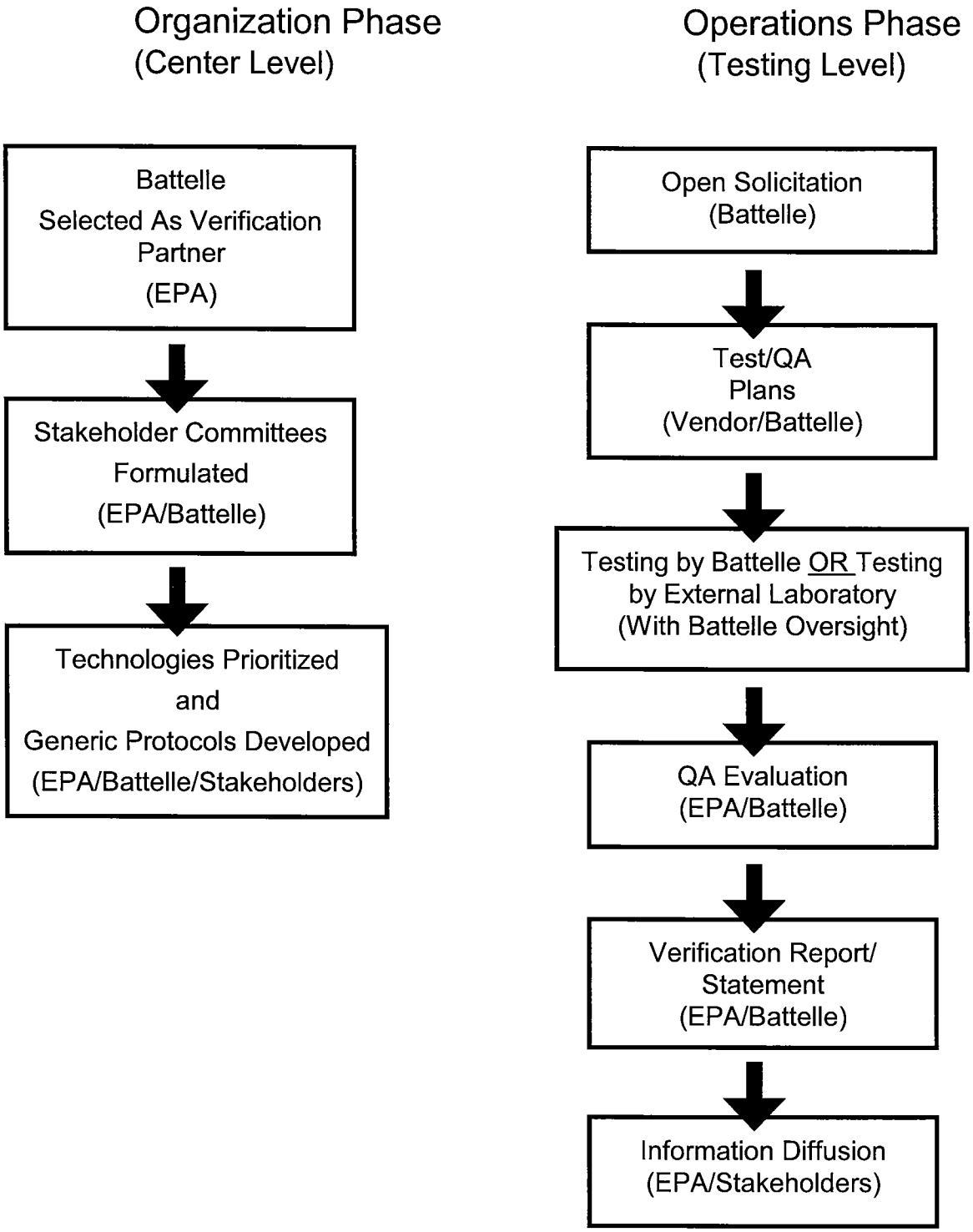

Figure 2.0 Systematic Planning of Verification Tests

- Quarterly reports to the EPA ETV program.

2.7.3 Planning Personnel

Verification test planning shall be coordinated by Battelle among the participating organizations including EPA, the stakeholders, the vendors, and any testing organizations and laboratories participating in the test. Battelle with the concurrence and oversight of the EPA Center Manager shall identify the planning roles of the participants, and shall conduct planning activities by shared communication via teleconference, video conference, and in-person meetings, as appropriate, and within the constraints of budget

2.7.4 Existing Data

Existing data may be used for planning, subject to the individual rules set up by each test.

2.8 DESIGN OF TECHNOLOGY VERIFICATION OPERATIONS

2.8.1 Design Process

The design process produces a test/QA plan based upon the data quality objectives for the verification of the technology performance.

2.8.1.1 Design Technique. In designing verification tests, Battelle staff uses consensus-accepted verification testing design including statistical methods, as appropriate. The design takes into account constraints of time, scheduling, and resources. All relevant activities pertaining to environmental data operations shall be identified, as well as performance specifications and the appropriate controls.

2.8.1.2 Field and Laboratory Equipment and Methods. During the design process, the appropriate field and laboratory equipment which were identified during planning for the testing of the technology verification performance, are incorporated. Appropriate test methods and operating parameters are specified.

2.8.1.3 Sampling and Analysis. If samples for analysis are taken in the field, they are handled according to procedures specified in the test/QA plan. The oversight responsibility of Battelle is to determine that the approved systems and plans contain adequate procedures for handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples to prevent damage, loss, deterioration, artifacts, or interferences. Battelle will provide adequate chain of custody procedures, if they are required. The following sampling and analysis design parameters should be addressed in the test/QA plan.

- Experiments to be conducted, the baseline parameters, the number of replicate tests, and the controls.
- Sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody (if sampling is performed).

- Sample locations, storage conditions, and holding times.
- Analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate, and as identified in the planning process.
- Methods and procedures to ensure the test produces traceable data of known and acceptable quality.
- Field and/or laboratory QA/QC activities.
- Requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data.

2.8.1.4 Assessments. Assessments incorporated into the design include self-assessments (internal audits) by Battelle and independent assessments by EPA. The assessments identified in the planning process are incorporated into the design. The type and minimum number of assessments are identified in Section 3.0.

2.8.2 Generic Verification Protocol, Test/QA Plans, and Standard Operating Procedures

Three types of planning documents have been identified for operation of an ETV Center: the generic verification protocol, the test/QA plan, and Standard Operating Procedures (SOPs). The generic verification protocol defines the general process by which a technology is invited, selected, tested, and reported. The test/QA plan give the specific information needed to conduct a verification test. If another level of detail is required for describing test activities, for example operation of an instrument, a SOP will be written and attached to the test/QA plan.

2.8.2.1 Generic Verification Protocol. The Battelle Center Manager will be responsible for assuring that the generic verification protocol is prepared and transferred to the EPA ETV Quality Manager and stakeholders for review. The issues that may be addressed in the generic verification protocol are the following:

- General description of the Center
- Responsibilities of all involved organizations
- Experimental design
- Equipment capabilities and description
- Description and use of field test sites
- Description and use of laboratory test sites
- QA/QC
- Data handling
- Requirements for other documents
- Health and safety
- References.

2.8.2.2 Test/QA Plans. Test/QA plans are the responsibility of the Battelle Center Manager and are reviewed by the Battelle Quality Manager and EPA ETV Quality Manager. The generic verification protocol is incorporated by reference. Appropriate guidance for writing test/QA plans is available in EPA/QA G-5, *Guidance for Quality Assurance Project Plans*. Planned changes to the

test/QA plan are made by amendment. Deviations from the plan must be fully documented including, date and description of deviation, and impact on the verification test. Elements of the test/QA plan include the following, although not all elements listed are appropriate to every test:

- Title and approval sheet
- Table of contents, distribution list
- Test description, test objectives
- Identification of the critical measurements, data quality objectives, data quality indicator goals, schedule, milestones
- Test (including QA) organization and responsibilities
- Documentation and records
- Experimental design
- Materials and equipment
- Sampling procedures
- Sampling handling and custody
- Analytical procedures
- Test-specific procedures for assessing data quality indicators
- Instrument calibration and frequency
- Data acquisition and data management procedures
- Internal systems audits
- Internal performance audits (where applicable)
- Corrective action procedures (response actions to audit findings)
- Assessment reports to EPA
- Data reduction, data review, data validation, data reporting
- Reporting of data quality indicators for critical measurements
- Limitations of the data.

2.8.2.3 Standard Operating Procedures. The follow topics, from EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)*, may be included (or a reference provided) in the standard operating procedure:

- Scope and applicability
- Summary of procedures
- Definitions (acronyms, abbreviations, etc.)
- Personnel qualifications
- Health and safety warnings (Warn of activities which could result in possible personal injury)
- Cautions (Warn of activities which could damage equipment, degrade samples, or invalidate results)
- Apparatus and materials
- Calibration
- Sample collection, sample labeling, sample tracking
- Handling and preservation of samples
- Interferences
- Sample preparation and analysis
- Data acquisition, calculation, and reduction

- Requirements for computer hardware and software used in data reduction and reporting
- Data management and records management.

2.9 IMPLEMENTATION

2.9.1 General

Technology performance verifications are implemented according to the test/QA plans and technical documents (e.g. Standard Operating Procedures) prepared during planning. Test personnel have access to the approved planning documents, approved changes to planning documents, and all referenced documents. When a prescribed sequence for the work is defined during the planning stages, work performed shall follow that sequence. All implementation activities are documented. Suitable documents are bound notebooks, field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). All documentation is implemented as described in the planning documents. All implementation activities are traceable to the planning documents and traceable to test personnel.

2.9.1.1 Conformance of implementation to planning is accomplished by following approved documents for the Battelle quality system implementation, verification testing, and for any field and laboratory technical operations.

Work on individual verification tests is not initiated until the approved test/QA plan is in place.

When work cannot be implemented according to the approved planning and test document, Battelle shall be responsible for providing a written amendment to the test/QA plan or deviation report for the test records. Amendments are produced for changes that are made to the test/QA plan before the proposed change is begun. Amendments must be approved internally by the Battelle Verification Testing Leader and Quality Manager. Following approval, the amendment will be distributed to all internal personnel holding a copy of the parent test/QA plan and the EPA ETV Quality Manager. A deviation report is produced for any changes to the test/QA plan that occurred during the test. Deviation reports must be retained in the verification test records and summarized in the verification test report. Frequent deviations from established procedures should result in a retrospective review of the written document and possible revision. Amendments and deviations will include all the information displayed on the example forms shown in Appendix III.

All persons responsible for performing verification testing and those participating vendors shall receive copies of the current revision of the test/QA plan and associated documentation provided by Battelle.

Current versions of test/QA plans and any applicable methods and SOPs are required to be physically in place at each technology verification testing site.

2.9.1.2 Battelle oversight and inspection of a verification test shall be provided by the Battelle Quality Manager or designee at intervals prescribed in each test/QA plan. This frequency, at a minimum, will be once for each verification test of a technology category. To verify full implementation of the test/QA plan, the inspection will include the testing process and any documentation associated with the process, such as sample tracking records; instrument maintenance and calibration; sample preparation and actual analysis; and data records. The Battelle Quality Manager will provide a written report, verify the completion of any corrective actions needed, and retain a copy of the report with permanent Battelle Quality Manager records. The EPA Center Manager will be included in the routing of the inspection results and a written copy provided to both the EPA Center Manager and ETV Quality Manager.

2.9.2 Implementation Procedures

2.9.2.1 Testing procedures shall be documented in approved test/QA plans and SOPs. Testing personnel, by virtue of training requirements described in this QMP, shall demonstrate proficiency of performance and knowledge of QA and Center requirements for the verification test operations.

2.9.2.2 Content requirements for testing procedures may include those of existing Battelle Standard Operating Procedures (SOPs) or other referenced documents.

2.9.2.3 Following the signing of the test/QA plan and before the initiation of testing, a test kickoff meeting will be held by the Verification Testing Leader. The Battelle Center Manager, Verification Testing Leader, Battelle Quality Manager, and all Battelle technical staff that will be utilized for the verification test will attend the kickoff meeting. Subjects to be discussed at the meeting will include, but not be limited to, a general overview of the test/QA plan, staff assignments, schedules, and assessments (QMP Section 3.0).

2.9.2.4 Review of technical Center-specific procedures shall be done by personnel technically competent with respect to the procedure. Time must be allowed for the composition, review, and approval of technical procedures to be completed in advance of the actual performance.

2.9.3 Implementation Monitoring

2.9.3.1 Routine monitoring during implementation of individual verification tests will be prescribed at a minimum frequency/interval in the test/QA plan. Specifically, the test/QA plan will address:

- A routine monitoring schedule and,
- The required specifications of performance, or particular aspects of the process, that are determined to be critical for monitoring.

2.9.3.2 Monitoring the work process is conducted by the Battelle Quality Manager or designee and is done to:

- Ensure satisfactory performance based on requirements,
- Ensure required actions (as specified in implementation documents) are performed so that routine measurements meet specifications,
- Ensure preventive maintenance is performed and documented as specified in facility and study records,
- Ensure calibrations are performed as planned and prescribed,
- Ensure corrective actions are implemented and documented as planned in response to items of nonconformance.

3.0 ASSESSMENT AND RESPONSE

3.1 SCOPE

3.1.1 Assessments shall be planned, scheduled, conducted, and reported in order to measure the efficacy of the Battelle quality system.

3.1.2 Assessment and response elements shall include assigning appropriate, qualified persons to conduct assessments at planned, scheduled intervals; having provisions for timely responses and implementation of corrective actions if needed; and completing the evaluation process with written reports to technical and management staff.

3.1.3 Assessment types, responsibility, and schedule for the AMS Center based upon Table 3.0, are defined as follows:

Management Systems Review, a qualitative evaluation by EPA to verify adequacy of management procedures. This assessment is the responsibility of the EPA ETV Quality Manager and is required once during the conduct of the ETV AMS Center.

Technical Systems Audit, a process by which the quality of a verification test is assessed. Conformance with the test/QA plan and associated methods and/or Standard Operating Procedures is the basis for this assessment. The Battelle Quality Manager conducts a technical systems audit at least once during each verification test. The EPA ETV Quality Manager conducts an independent technical systems audit at least two times for the AMS Center.

Performance Evaluation Audits, a process by which the quality of a measurement is assessed. The type and frequency of performance evaluation self-audits to be performed by the Battelle Verification Testing Leader or designee (and assessment of results by the Battelle Quality Manager) are specified in the test/QA plan for each verification test. The need for independent performance evaluation audits will be determined by the EPA ETV Quality Manager.

Audits of Data Quality, a process by which the accuracy of data calculations and reporting is assessed. The Battelle Quality Manager will audit at least 10% of all verification data. The need for independent audits of data quality will be determined by the EPA ETV Quality Manager.

3.2 GENERAL REQUIREMENTS

3.2.1 Each assessment must be fully documented. The Battelle Quality Manager will archive all internal assessment reports generated on the AMS Center.

Each assessment must be responded to by the appropriate level of management. The Battelle quality assessment reports shall require a written response by the person performing the

Table 3.0 Assessments for the AMS Center

Level	Assessment Tool	Assessors	Assessees/ Responders	Subject of Assessment	Minimum Frequency	Reason for Assessment	Report Reviewed by
Center	management systems review	EPA ETV Quality Manager	Battelle	center QMP	once; thereafter, as requested	assess quality management practices of verification partner	EPA directors of quality assurance EPA Center Manager Battelle Center Manager ETV Program Coordinator
Center	technical systems audits	Self Battelle Quality Manager Independent EPA ETV Quality Manager	Battelle	test/QA plans	Self Once per verification test Independent twice per center	assess quality of technical verification operations	EPA Center Manager EPA ETV Quality Manager Battelle Center Manager
Center	performance evaluation audits	Self Battelle Quality Manager Independent EPA ETV Quality Manager	Battelle	test/QA plans	Self As specified in test/QA plan Independent for each center, as applicable	assess measurements performance	EPA Center Manager EPA ETV Quality Manager Battelle Center Manager
Center	audits of data quality	Self Battelle Quality Manager Independent EPA ETV Quality Manager	Battelle	raw data and summary data	Self At least 10% of the verification data Independent for each center, as applicable	assess data calculations and reporting	EPA Center Manager EPA ETV Quality Manager Battelle Center Manager

inspected activity, and acknowledgment of the assessment by the Battelle Verification Testing Leader and the Battelle Center Manager.

3.2.3 Corrective action must be documented and approved on the original assessment report, with detailed narrative in response to the assessor's finding. Initials and date are required for each corrective action response. Acknowledgment of the response will be provided by the Battelle Verification Testing Leader and Battelle Center Manager.

3.2.4 Implementation of corrective actions must be verified by the Battelle Quality Manager or designee to ensure corrective actions are adequate and have been completed. This will be done in real-time if corrective actions can be immediately performed and signed off on the assessment report; or, should the corrective action require additional approvals not immediately available on-site, the Battelle Quality Manager or designee may need to repeat the inspection in order to corroborate the implementation and effectiveness of the corrective action.

3.3 PLANNING AND PROCEDURES

3.3.1 Assessment Planning

Assessment planning is performed by Battelle's Quality and Center Managers prior to the actual performance of any assessments. Planning the assessment scope helps provide the type of evaluation information needed to determine whether procedural compliance and technical requirements are being met during verification testing.

Assessment planning by Battelle shall include a kickoff meeting with the verification testing team where at least the following information will be discussed:

- Assessment plan format,
- Schedule of assessment(s),
- Notification to affected parties,
- Specific assessment requirements (personnel lists, equipment lists, and availability of test/QA plans),
- Assessment checklist consistent with requirements,
- Assessment report format,
- Follow-up procedures for corrective action, including debriefing and discussion of possible resolutions,
- Corrective action guidelines to facilitate completion of the reported assessment,
- Appropriate management signature approval of the reviewed assessment report.

3.3.2 Personnel Qualifications for Assessment

The principal Battelle inspector shall be the Battelle Quality Manager, who will have an extensive quality assurance laboratory and field inspection background, and technical and management experience, and who will be directly familiar with the AMS Center assessment requirements. Should the need arise, the Battelle Quality Manager will designate an individual to perform scheduled assessments, based upon that person's technical skill and knowledge of QMP compliance requirements and test/QA plan specifications. Battelle personnel conducting assessments shall have the responsibility and authority to:

- identify and document problems affecting the quality of verification results,
- propose recommendations for resolving these problems,
- independently confirm implementation and effectiveness of solutions.

3.3.3 Stop Work

Assessor responsibility and authority to stop work during the AMS Center for safety and quality considerations is delegated to Battelle, who must ensure compliance with all onsite federal, state, and local safety policies during the performance of verification testing.

Should it be determined during an assessment that adverse health effects could result, or that test objectives of acceptable quality cannot be achieved during performance of verification testing, the Battelle Quality Manager is responsible for immediately notifying the Battelle Center Manager of the need to consider a stop work order. The Battelle Center Manager shall then direct the AMS staff accordingly.

Should any AMS staff suspect compromise to personal health or test objectives during the conduct of verification testing, that staff member shall immediately contact the Battelle Verification Testing Leader, who shall through vested authority from the Battelle Center Manager, issue the stop work order and subsequently notify the Battelle Center Manager.

The EPA Center Manager and EPA ETV Quality Manager are also delegated to notify the Battelle Center Manager to facilitate a stop work order if work of inadequate quality is discovered.

Documentation of any stop work order and corrective action implemented is required and shall be maintained as part of the Battelle quality records, with a copy provided to the EPA ETV Program and Quality Managers.

3.3.4 Internal Assessment Reporting

Authority to effectively report internal technical system audits, performance evaluation audits, and audits of data quality is assigned to the Battelle Quality Manager or designee. These reports should:

- Identify and document problems that affect quality and the achievement of objectives required by the QMP, test/QA plan, and any associated Standard Operating Procedures,
- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products,
- Propose recommendations (if requested) for resolving problems that affect quality,
- Independently confirm implementation and effectiveness of solutions,
- Provide documented assurance (if requested) to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

3.3.5 Response

Responses to TSA adverse findings shall be addressed within 10 working days after the TSA is completed. However, it is expected that findings that have a direct impact on the conduct of a verification test will be corrected immediately following notification of the finding.

Responses to each adverse finding shall be documented in the assessment report (QMP Section 3.3.4). Ideally, assessment reports will provide space after each adverse finding for a response to be recorded. The response will indicate the corrective action taken or planned to address the adverse finding. The response should be signed and dated by the staff responsible for implementing the corrective action.

Any corrective action that cannot be immediately implemented should be verified following completion by the Battelle Quality Manager or designee. Once all corrective action associated with an assessment report has been taken, the Battelle Quality Manager or designee will initial the corrective action in the assessment report thus documenting verification of the corrective action. Any impact that an adverse finding had on the quality of verification test data should be addressed in the verification test report.

The TSA assessment report, with responses to adverse findings recorded within, will be sent to EPA within 10 working days after the Battelle Quality Manager has verified all corrective actions.

3.4 DATA VALIDATION

Validation is based on the performance measures for the test specified during the design process. The usability of a verification report and statement is determined relative to how well it determines the performance of the tested technology under the conditions of testing. Any limitations on the data and recommendations for limitations on data usability are documented in the data audit report and the ETV verification report.

3.5 REPORT REVIEW

Review and approval procedures for verification reports and statements are given in Table 2. Verification reports are peer-reviewed by external reviewers and verification statements are signed by an EPA laboratory director.

3.6 QUALITY IMPROVEMENT

3.6.1 Policy

A continuous quality improvement process is considered essential for Battelle staff to develop a more responsive quality system in all aspects of technical and management activities.

3.6.2 Annual QMP Review

An annual review of the QMP for the AMS Center shall be conducted by the Battelle Quality Manager and technical and management staff in order to incorporate improvements to the quality system process.

Any revisions to the QMP will be compiled by the Battelle Quality Manager for review, approval, and distribution. The QMP review will be documented by the Battelle Quality Manager and Battelle Center Manager by signing and dating the revised QMP routed for review and approval.

3.6.3 Problem Identification and Resolution

Detecting and correcting quality system problems is a result of qualified AMS Center technical and management staff implementing not only this QMP, but also the test/QA plan and other procedures. All staff are encouraged to identify problems and offer solutions to problems in the following quality areas:

- Adequacy of the quality system, as defined in the QMP,
- Consistency of the quality system,
- Implementation of the quality system to specific verification tests,
- Correction of quality system procedures,

- Completeness of documented information,
- Quality of data,
- Quality of planning documents, such as the test/QA plans,
- Implementation of the work process.

Cause and effect relationships of significant problems shall be documented by the Battelle Quality Manager. When problems are reported to the Battelle Quality Manager, attempts to determine the root cause based on cause and effect during performance of planned and documented procedures will be made through intensified observations of testing activities and audits of test data.

Collaboration with trained technical/management staff associated with or performing the activity can provide insight and determine whether any of the following is required:

- A test/QA plan change,
- A management system change, or
- A quality system change with the AMS Center.

Assessment reports can also serve as tools to determine cause and effect relations of significant problems that might require testing protocol, management system, or quality system changes. Continual monitoring and evaluation by the EPA ETV Quality Manager, for example, may indicate trends or common and recurring problems for an entire technology evaluation. In this case, the situation is immediately communicated to the ETV Program Coordinator, who then provides information and any corrective actions to the EPA Center Manager.

Root cause determination is immediately reported by Battelle to the EPA Center Manager prior to any planned implementation of preventative measure. Once the root cause determination is verified, appropriate actions can be planned, documented, and implemented by the AMS Center staff.

3.6.4 Ongoing Quality Improvement

Quality improvement action is ongoing in the Battelle quality system, where quality issue action items can be reviewed by all levels of line management at periodic continuous improvement meetings. Quality processes are continually monitored and both short-term and long-term quality issues are identified through customer feedback and client involvement, peer review and internal lessons learned, and monthly program reviews

APPENDIX I

NAMES, ADDRESSES, AND PHONE NUMBERS OF BATTELLE AMS CENTER KEY STAFF

KEY BATTELLE AMS CENTER STAFF

Battelle Center Manager:

Ms. Karen Riggs
505 King Avenue
Columbus, OH 43201
Phone: 614-424-7379
Fax: 614-424-3638
email: riggsk@battelle.org

Battelle Quality Manager:

Mr. Zachary J. Willenberg
505 King Avenue
Columbus, OH 43201
Phone: 614-424-5795
Fax: 614-424-3638
email: willenbergz@battelle.org

Verification Testing Leaders:

Dr. Thomas J. Kelly
505 King Avenue
Columbus, OH 43201
Phone: 614-424-3495
Fax: 614-424-3638
email: kellyt@battelle.org

Ms. Amy Dindal
5772 Franklin Trail
Liberty Township, OH 45011
Phone: 513-779-4553
Fax: 513-779-4553
email: dindala@battelle.org

Stakeholder Involvement Leader:

Ms. Gretchen Hund
Battelle
P.O. Box 5395 S-1-48
Seattle, WA 98105-5428
Phone: 206-528-3338
Fax: 206-528-3552
email: hundg@battelle.org

Promotion and Communications Leader:

Ms. Helen Latham
505 King Avenue
Columbus, OH 43201
Phone: 614-424-4062
Fax: 614-424-5601
email: lathamh@battelle.org

APPENDIX II

ETV VERIFICATION STATEMENT

THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

ETV

EPA
U.S. Environmental Protection Agency

Battelle
... Putting Technology To Work

ETV Joint Verification Statement

TECHNOLOGY TYPE:	**Continuous Emission Monitor**
APPLICATION:	**MEASURING MULTIPLE METALS IN STACK GAS**
TECHNOLOGY NAME:	**XCEM Multi-Metals Continuous Emission Monitor**
COMPANY:	**Cooper Environmental Services**
ADDRESS:	**10170 S.W. Nimbus Avenue PHONE: 503-624-5730** **Suite H-5 FAX: 503-624-2120** **Portland, OR 97223**
WEB SITE:	
E-MAIL:	**JohnsenCES@aol.com**

The U.S. Environmental Protection Agency (EPA) has created the Environmental Technology Verification (ETV) Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by substantially accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies.

ETV works in partnership with recognized standards and testing organizations; with stakeholder groups that consist of buyers, vendor organizations, and permitters; and with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

The Advanced Monitoring Systems (AMS) Center, one of six technology centers under ETV, is operated by Battelle in cooperation with EPA's National Exposure Research Laboratory. The AMS Center has recently evaluated the performance of the Cooper Environmental Services X-ray based continuous emission monitor (XCEM). This verification statement provides a summary of these test results.

VERIFICATION TEST DESCRIPTION

The objective of the verification test was to quantitatively evaluate the performance of the XCEM under real-world conditions. Verification testing took place at the Tooele Army Depot (TEAD) Building 1320 deactivation incinerator. The XCEM was tested for its ability to measure five elements found in the feedstream—antimony (Sb), barium (Ba), cadmium (Cd), chromium (Cr), and lead (Pb), as well as arsenic (As), mercury (Hg), nickel (Ni), and zinc (Zn). Except for Pb, the stack gas levels of these target metals were prepared by spiking metal solutions into the stack gas at the base of the stack. Stack gas metal concentrations were simultaneously determined by the XCEM and by two EPA Method 29 (M29) sampling trains. The M29 trains sampled for two hours, while XCEM data, which are recorded every 20 minutes, were averaged over each M29 run. A total of 13 dual M29 runs were performed by the U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) Air Quality Surveillance Program. In all cases, when reference method data were being taken, the spiking of the indicated metals was held constant throughout the entire sampling period to allow comparisons of XCEM data to reference method data under constant conditions. CHPPM's Directorate of Laboratory Services conducted laboratory analysis of the M29 sampling trains. The test activities provided data for verifying the relative accuracy (RA); correlation with reference method; precision; span, zero, and internal standard drift; bias; and response time. RA was determined by comparing M29 results to simultaneous XCEM results averaged over the M29 sampling periods. The RA of the XCEM with respect to M29 was assessed by

$$RA = \frac{\left|\bar{d}\right| + t^{\alpha}_{n-1}\frac{S_d}{\sqrt{n}}}{\bar{x}} \times 100\%$$

Where d refers to the difference between corresponding M29 and XCEM results, n is the number of runs, and $\bar{x}$ is the average M29 result. S_d denotes the sample standard deviation of the differences, while t^{α}_{n-1} is the t value for the $100(1-\alpha)^{th}$ percentile of the distribution with n-1 degrees of freedom. The RA was determined for an α value of 0.025 (i.e., 97.5% confidence level, one-tailed). Correlation of XCEM and M29 results was calculated using the same data used to calculate RA. Precision of the XCEM was calculated in terms of the percent relative standard deviation (RSD) of successive XCEM readings during periods of stable metal concentrations.
Drift was checked by automated daily XCEM span and zero QA measurements. Bias relative to M29 was identified using EPA Method 301 (M301) protocols. Response time was determined as the time between the start of one XCEM sampling period and the beginning of the next sampling period.

Battelle and EPA provided QA oversight of verification testing. Battelle QA staff conducted a data quality audit of 10% of the test data, and Battelle's Quality Manager performed an internal technical systems audit of the verification test during testing at the TEAD incinerator. Battelle, with the assistance of CHPPM staff, performed a series of performance evaluation audits to check the quality of reference measurements made in the verification test. A technical systems audit report was submitted to EPA Quality Management staff.

TECHNOLOGY DESCRIPTION

The XCEM extracts a sample of stack gas and concentrates the metals of interest on a chemically treated filter tape. Following collection, the filter tape advances, moving the sample spot to an analysis area where a laboratory-grade X-ray fluorescence (XRF) instrument is used to determine metal mass. The system is automated and can produce concentration data every 10 to 20 minutes for 19 elements of interest. The XCEM components include the extraction system, the sampling and analysis system, and the control system. The XCEM extraction system collects a representative stack gas sample from the stack and transports the sample to the filter tape. Upon entrance into the XCEM housing, the stack gas passes through a heat-traced stilling chamber that expands the tubing diameter and slows the gas velocity. An eductor, located downstream of the stilling chamber, is used to pull the stack gas through the extraction system. Of the two to three standard cubic feet per minute that pass through the stilling chamber, a sub-sample of approximately 0.8 liter per minute is extracted and directed through a filter

tape, concentrating the metals sample for analysis. Following filtration, the stack gas is subsequently transported to the XCEM chassis where drying and volume determination take place. The excess (i.e., unfiltered) stack gas is transported out of the stilling chamber through a flowmeter and is vented or returned to the stack. The sampling cassette holds a four-week supply of filter tape on a reel-to-reel system that is automated to accurately move the tape from the sampling to the analysis position. Sampling and analysis occur simultaneously, resulting in a continuous monitoring system that produces metal concentration values every 10 to 20 minutes. Metal mass on the filter is determined using a modified ThermoNoran QuanX energy dispersive XRF analyzer. The XCEM has an automated check for internal standard drift that measures a palladium (Pd) standard with each XCEM analysis.

The XCEM is controlled by a personal computer using a custom WonderWare software interface. All day-to-day functions of the XCEM are automated, including flow and temperature control, concentration determination, and QA routines. Flow, temperature, concentration, pressure, and error messages are automatically recorded in a secure database. The data can be imported into Excel or an equivalent program for subsequent analysis. Flows, temperatures, concentrations, and pressure are logged in real time on the screen computer monitor.

VERIFICATION OF PERFORMANCE

Relative Accuracy: The XCEM relative accuracy for Cd, Cr, and Ni was less than 26% (less than 20% calculated for nine runs). The remaining metals (As, Ba, Hg, Pb, Sb, and Zn) had RA values between 37 and 67%. The RA for Pb was 36.7% calculated for nine runs. The reported XCEM concentrations were uniformly high for As. The XCEM was consistently low for Zn, Ba, and Sb. XCEM Hg readings were very low at the start of each test day, rising gradually until they stabilized. The best agreement of XCEM and M29 Hg results (within about 20%) was found with M29 runs conducted late in the test day, when XCEM readings had stabilized.

Correlation with Reference Method: Correlation of XCEM and M29 results was calculated for five elements that varied enough during the test to justify this comparison. For Ni, Pb, Sb, and Zn, r^2 values exceeding 0.95 were found, although the r^2 value for Pb decreased to 0.75 when the high Pb levels in Runs 1 and 2 were excluded. For Hg, an r^2 value of 0.39 was found.

Precision: The XCEM's precision ranged from 6 to 21% over the nine target metals. This precision includes variability in the metals injection and the test facility, as well as in the XCEM itself.

Span, Zero, and Internal Standard Drift: XCEM span and zero drift were assessed over the four test days. Daily span readings of Cd, Cr, Hg, and Pb exhibited RSD values of 0.47 to 2.33% and no significant trends over time. Zero readings for all four elements were near or below the respective detection limits on all test days. The RSD of the XCEM's Pd internal standard was approximately 2.5%.

Bias: The XCEM results showed statistically significant positive or negative bias relative to M29 results for all the target metals, based on M301 procedures.

Response Time and Other Parameters: The XCEM functioned in an automated manner and automatically recorded concentrations, temperatures, flow rates, and QA data. It exhibited no mechanical problems, had an effective up time of 100%, and a response time of 20 minutes.

original signed by Gabor J.Kovacs 5/4/02
Gabor J. Kovacs Date
Vice President
Environmental Sector
Battelle

original signed by Gary J. Foley 8/15/02
Gary J. Foley Date
Director
National Exposure Research Laboratory
Office of Research and Development

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APPENDIX III

AMENDMENT AND DEVIATION FORMS

TEST/QA PLAN AMENDMENT

TEST/QA PLAN TITLE AND DATE:

AMENDMENT NUMBER: _____

EFFECTIVE DATE: _____

PART TO BE CHANGED/REVISED:

CHANGE/REVISION:

REASON FOR CHANGE:

APPROVED BY:

_____	_____
Battelle Verification Testing Leader	Battelle AMS Center Quality Manager
_____	_____
DATE	DATE

Required Distribution - All individuals/organizations listed on distribution for the applicable Test/QA Plan, including but not limited to:

Battellle AMS Center Management
Battelle AMS Center Testing Staff
Battelle AMS Center Quality Manager
Subcontractors (if any)
Verification Test Partners (if any)
EPA/ETV AMS Center Management
EPA/ETV Quality Staff
Vendors

Distribution must be documented

TEST/QA PLAN DEVIATION REPORT

TEST/QA PLAN TITLE AND DATE:

DEVIATION NUMBER: _____

DATE OF DEVIATION:

DESCRIPTION OF DEVIATION:

CAUSE OF DEVIATION:

IMPACT OF DEVIATION ON THE STUDY:

CORRECTIVE ACTION:

ACKNOWLEDGED BY:

_____	_____
Battelle Verification Testing Leader	Battelle AMS Center Quality Manager
_____	_____
DATE	DATE